Attorney Docket No. 82062-0169 Serial No. 10/522,030

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

 (Currently amended) A <u>doubled coated</u> stent <u>for a patient's body</u> comprising a <u>first</u> <u>coating designed to adhere to a vessel wall of the patient's body and a second coating in contact</u> with the stent:

<u>said first coating containing based on a polymer of hyaluronic acid characterized in that</u> the <u>said hyaluronic acid polymer</u> is an ester derivative of hyaluronic acid;

said first coating containing a first quantity of a pharmacologically active ingredient; said active ingredient associated with the polymer; and therefore the first coating acts as a first reservoir for controlled delivery of the pharmacologically active ingredient and the hyaluronic acid over a first period of time;

said second coating comprising a synthetic hydrophobic polymer;

said second coating containing a second quantity of the pharmacologically active ingredient over a second period of time, and therefore acts as a second reservoir for the active ingredient to further extend the delivery period of the active ingredient:

wherein said second coating being applied directly to the stent; and said first coating being applied over the second coating; thereby providing a hydrophobic layer beneath the hyaluronic acid polymer.

wherein the ester-derivative of hyaluronic acid is not sulfated and wherein the hylauronic acid ester derivative has all or some of the carboxyl groups of the hylauronic acid esterified with alcohols selected from those of the aliphatic, arylaphatic, cycloaliphatic and heterocyclic series and wherein the degree of esterfication of the hylauronic acid ester derivative varies from 50% to 100% of the carboxyl group in the hylauronic acid.

- 2. (Cancelled)
- 3. (Previously presented) A stent according to claim 1, in which:

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when the alcohols are of the aliphatic series they are selected from straight or branched saturated or unsaturated alcohols having from 2 to 12 carbon atoms, optionally substituted with one or more groups selected from hydroxide, amine, aldehyde, mercaptan or carboxyl groups or groups derived from these such as for example esters, ethers, acetals, ketals, thioethers, thioesters, carbamides; in particular when the alcohols are saturated aliphatic alcohols they are selected from methyl, ethyl, propyl, isopropyl, normal butyl, isobutyl, ter-butyl, amyl or pentyl alcohols; when the alcohols are bivalent aliphatic alcohols they are selected from the alcohols ethylene glycol, propylene glycol, butylene glycol, and when the alcohol is a trivalent aliphatic alcohol it is preferably glycerine; when the alcohols are amino alcohols, they are selected from aminoethanol, aminopropanol, aminobutanol and their dimethylene- or diethyleneamine derivatives, piperidine ethanol, pyrrolidine ethanol or piperazine ethanol; when the alcohols are carboxy alcohols, they are selected from lactic, tartaric, maleic or glycolic acids; when the alcohols are unsaturated aliphatic alcohols they are preferably allyl alcohols.

when the alcohols are of the arylaliphatic series they are selected from those having a benzene optionally substituted with from 1 to 3 methyls or hydroxyls or halogen atoms, in particular fluorine, chlorine, bromine and iodine, and in which the aliphatic chain has from 1 to 4 carbon atoms and is optionally substituted by one or more groups selected from primary amine groups, mono- or dimethylated groups or from pyrrolidine or piperidine groups, in particular they are benzyl alcohol or phenylethyl alcohol.

when the alcohols are of the cycloaliphatic series they are selected from those mono- or polycyclic alcohols containing from 3 to 34 carbon atoms and optionally containing from 1 to 3 hetero atoms selected from O, S, N and optionally substituted with one or more groups selected from hydroxyl, amine, aldehyde, mercaptan or carboxyl groups or groups derived from these such as for example esters, ethers, acetals, ketals, thioethers, thioesters, carbamides; in particular when the cycloaliphatic alcohols are monocyclic they are selected from those containing from 5 to 7 carbon atoms, optionally substituted with one or more groups selected from hydroxyl, methyl, ethyl, propyl, isopropyl, and in particular they are cyclohexanol, cyclohexandiol, inositol or menthol.

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- 4. (Cancelled).
- 5. (Previously presented) A stent according to claim 1 in which the degree of esterification varies from 70% to 100% of the carboxyl groups in the hyaluronic acid.
- (Original) A stent according to claim 1, in which the alcohol is benzyl alcohol and the degree of esterification is equal to 100% of the carboxyl groups in the hyaluronic acid.
- (Original) A stent according to claim 1, in which the alcohol is benzyl alcohol and the degree of esterification is equal to 75% of the carboxyl groups in the hyaluronic acid.
- (Currently amended) A stent according to claim 1, in which a pharmacologically active ingredient is associated with the hyaluronic acid polymer coating wherein the ester derivative of hyaluronic acid is not sulfated.
- 9. (Previously presented) A stent according to claim 8 in which the active ingredient associated with the hyaluronic acid polymer coating is selected from the group consisting of active ingredients having an anti-inflammatory, antiproliferative, antiimigratory, immunosuppressants, and antimigratory and immunosuppressant action.
- 10. (Previously presented) A stent according to claim 8 in which the active ingredient is 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamide methane sulphonate.
- 11. (Original) A stent according to claim 9, in which when the active ingredient is an active ingredient having an anti-inflammatory action it is associated with the hyaluronic acid polymer coating in a quantity of between 0.001 mg and 10 mg.
- 12. (Original) A stent according to claim 9, in which when the active ingredient is an active

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ingredient having an anti-proliferative action it is associated with the hyaluronic acid polymer coating in a quantity of between 0.0001 mg and 10 mg.

13. (Original) A stent according to claim 9, in which when the active ingredient is an active ingredient having an anti-migratory action it is associated with the hyaluronic acid polymer coating in a quantity of between 0.0001 mg and 10 mg.

- 14. (Original) A stent according to claim 9, in which when the active ingredient is an immunosuppressant it is associated with the hyaluronic acid polymer coating in a quantity of between 0.0001 mg and 10 mg.
- 15. (Original) A stent according to claim 10, in which when the active ingredient is 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamide methane sulphonate, this is associated with the hyaluronic acid polymer coating in a quantity of between 0.001 mg and 10 mg.
- 16. (Currently amended) A stent according to claim 1, in which the <u>first coating has a thickness</u> thickness of the hyaluronic acid polymer coating on the stent varies from 0.5 microns to 40 microns, preferably between 1 and 30 microns, even more preferably between 5 and 10 microns.
- 17. (Currently amended) A stent according to claim 1 [[8]], in which the active ingredient and the hyaluronic acid are released from the hyaluronic acid polymer coating over a prolonged time.
- 18. (Previously presented) A stent according to claim 17, in which the active ingredient and the hyaluronic acid are released from the hyaluronic acid polymer coating in a time exceeding one month.

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19. (Previously presented) A stent according to claim 18, in which the active ingredient and the hyaluronic acid are released from the hyaluronic acid polymer coating within two weeks.

- 20. (Currently amended) A stent according to claim 1, comprising a middle layer of hyaluronic acid covalently bound to the first coating and second coating so that the layer is sandwiched in between the first and second coating comprising a layer of hyaluronic acid covalently bound to the surface of the stent itself and a coating of hyaluronic acid polymer as described in claim 1.
- 21. (Currently amended) A stent according to claim 1, wherein the first and second coatings deliver a controlled release of the pharmacologically active ingredient over a period of two months, the first coating degrading before the second coating further comprising a second-coating of a polymer having a hydrophobic nature with which a pharmacologically active ingredient is associated.
- 22. (Currently amended) A stent according to claim 20 wherein the middle layer is approximately 10 nanometers thick, in which the said polymer coating having a hydrophobic nature is applied directly to the surface of the stent, beneath the said coating based on hyaluronic acid ester-polymer.
- 23. (Currently amended) A stent according to claim [[21]] 1, in which the said-hydrophobic polymer having a hydrophobic nature has a contact angle with water which is greater than 60°.
- 24. (Currently amended) A stent according to claim 23 in which the <u>hydrophobic polymer having a hydrophobic nature</u> is selected from polymethyl methacrylate, polybutyl methacrylate, polyisobutylmethacrylate, olefinic polymers, polybutadiene, polyisoprene, poly(acrylonitrile-butadiene-styrene) or polyvinyl acetate.
- 25. (Currently amended) A stent according to claim 23 in which the polymer of the second

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coating of a hydrophobic nature is polystyrene.

26. (Currently amended) A stent according to claim [[21]] 1, in which the active ingredient associated with the <a href="hydrophobic">hydrophobic</a> polymer-eoating of a <a href="hydrophobic">hydrophobic</a> polymer-eoating of a <a href="hydrophobic">hydrophobic</a> in active ingredients having an anti-inflammatory, antiproliferative or antimigratory action and/or immunosuppressants.

- 27. (Currently amended) A stent according to claim [[21]] <u>1</u>, in which the said active ingredient associated with the polymer coating of a hydrophobic nature is 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamide methane sulphonate.
- 28. (Currently amended) A stent according to claim [[21]] 1, in which the quantity of the active ingredient associated with the polymer coating of a hydrophobic nature is between 0.0001 mg and 10 mg.
- 29. (Currently amended) A stent according to claim [[21]] 1, wherein said second coating has a thickness in which the thickness of the said polymer coating of a hydrophobic nature on the stent varies from 0.5 microns to 40 microns, preferably between 1 and 30 microns, even more preferably between 5 and 10 microns.
- 30. (Currently amended) A stent according to claim [[21]] 29, in which the active ingredient is released from the second coating said polymer coating of a hydrophobic nature in a time of one month.
- 31. (Currently amended) A stent according to claim [[21]] 1, in which the <u>first and second</u> quantity are the <u>same</u> active ingredient and the quantity of active ingredient associated with the said two polymer coatings respectively is the <u>same or different</u>.

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32. (Currently amended) A stent according to claim [[21]] 1, which further includes a layer of hyaluronic acid covalently bound to the polymer coating of a hydrophobic nature.

Cancel claims 33-42.

43 (New) The stent of Claim 1, wherein the first and second coatings have a combined thickness of about 20 microns and can deliver pharmacologically active ingredients for a period of about two months wherein the first coating degrades before the second coating, and each coating has about the same thickness.

44. (New) A doubled coated stent for a patient's body comprising a first coating designed to adhere to a vessel wall of the patient's body and a second coating in contact with the stent:

said first coating containing a polymer of hyaluronic acid characterized in that the hyaluronic acid polymer is an ester derivative of hyaluronic acid;

said first coating containing a quantity of a first pharmacologically active ingredient; said active ingredient associated with the polymer; and therefore the first coating acts as a reservoir for controlled delivery of the first pharmacologically active ingredient and the hyaluronic acid over a first period of time;

said second coating comprising a synthetic hydrophobic polymer;

said second coating containing a quantity of a second pharmacologically active ingredient over a second period of time, and therefore the second coating acts as a reservoir for controlled delivery of the second pharmacologically active ingredient and the hyaluronic acid over a second period of time;

wherein said second coating being applied directly to the stent; and said first coating being applied over the second coating; thereby providing a hydrophobic layer beneath the hyaluronic acid polymer.

45. (New) A stent according to claim 44, in which a pharmacologically active ingredient is associated with the hyaluronic acid polymer coating wherein the ester derivative of hyaluronic

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acid is not sulfated

46. (New) A stent according to claim 44, comprising a middle layer of hyaluronic acid

covalently bound to the first coating and second coating so that the layer is sandwiched in

between the first and second coating.

47. (New) A stent according to claim 44, in which the polymer of the second coating is

polystyrene.

48. (New) The stent of Claim 44, wherein the first and second coatings have a combined

thickness of about 20 microns and can deliver pharmacologically active ingredients for a period

of about two months wherein the first coating degrades before the second coating, and each

coating has about the same thickness.

49. (New) A stent according to claim 44, in which the active ingredient and the hyaluronic

acid are released from the hyaluronic acid polymer coating in a time exceeding one month.

50. (New) A stent according to claim 44, wherein the first and second coatings deliver a

controlled release of the pharmacologically active ingredient over a period of two months, the

first coating degrading before the second coating.

51. (New) A stent according to claim 44, in which the active ingredient is released from the

second coating in a time of one month.

52. (New) A stent according to claim 44, in which the first coating has a thickness between 5

and 10 microns.

53. (New) A stent according to claim 46 wherein the middle layer is approximately 10

nanometers thick.

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54. (New) A stent according to claim 53, wherein said second coating has a thickness

between 5 and 10 microns.